

Remarks

Applicants request consideration of the above-referenced patent application.

Amendments to Claims

New claims 19-27 have been added. Thus, claims 1-27 are pending.

Claims 1-15, 17, and 18 have been amended in this Amendment C. Applicants submit that these amendments and the new claims do not introduce new matter. More specifically:

The R² definitions in claims 1, 5, and 9 have been amended to define the recited heteroaryl as being pyridinyl, pyrazinyl, pyridazinyl, pyrimidinyl, thienyl, pyrrolyl, pyrazolyl, imidazolyl, oxazolyl, or isoxazolyl. This amendment is in accordance with the suggested amendments in the Office action, and supported by Applicants' specification at, for example, page 6, line 32 to page 7, line 2.

Claims 2-4 have been amended to expressly further encompass salts and esters of the recited compounds. These amendments are consistent with the language of claim 1, *i.e.*, the claim from which claims 2-4 depend.

Claims 2, 6, and 10 have been amended to remove substituent definitions that are redundant with the substituent definitions in claims 1, 5, and 9 (*i.e.*, the claims from which claims 2, 6, and 10 respectively depend).

Claim 8 has been amended to remove "prodrug".

Claim 9 has been amended to characterize the recited condition as being treatable by inhibiting $\alpha_v\beta_3$ integrin. This amendment is supported by Applicants' specification at, for example, page 6, lines 4-5; and page 8, lines 9-12.

Claim 9 has been amended to expressly further encompass the administration of esters or pharmaceutically acceptable salts of the compounds recited in claim 9. This amendment is supported by Applicants' specification at, for example, page 8, lines 9-17.

Claims 9 and 15 have been amended to remove the phrase "including a human". This amendment removes exemplary claim language, and does not narrow the scope of the claims. *See* MPEP §2173.05(d). Similarly, claims 13 and 14 have been amended to remove the phrases "including tumor angiogenesis" and "including restenosis". This amendment also removes exemplary claim language, and does not narrow the scope of the claims.

Claims 17 and 18 have been amended to be directed to a "combination pack". This amendment is supported by Applicants' specification at, for example, page 14, line 29 to page 15, line 1.

Other amendments simply rephrase the claims, remove redundancies or unnecessary terms, or correct grammatical or obvious errors. Applicants submit that such amendments do not affect the scope of the claims, and are permissible under MPEP §2163.07.

New claims 19-21 are each directed to a subset of the compounds recited in originally-filed claim 4. New claims 22-24 are each directed to a subset of the compounds recited in originally-filed claim 8. And new claims 25-27 are each directed to a subset of the compounds recited in originally-filed claim 12. As discussed below, Applicants have introduced these claims in accordance with the suggested amendments in the Office action.

Applicants reserve the right to pursue any canceled subject matter and/or any other subject matter disclosed in this application in one or more later-filed divisional and/or continuation applications.

Response to rejection of claims 1, 5, and 9 under 35 U.S.C. §112

Claims 1, 5, and 9 have been rejected under 35 U.S.C. §112 (1st Paragraph) for lacking support as to the heteroaryl definitions for R². Applicants request withdrawal of this rejection. Applicants submit that the claim language satisfies the written support requirement because the heteroaryl definition for R² in these claims is expressly recited in the specification at, for example, page 5, lines 9-16. *See* MPEP §2163.03. In addition, Applicants submit that one skilled in the art would be familiar with the term "heteroaryl", and could readily identify species falling within that term, particularly in this instance where Applicants' specification provides several representative examples of heteroaryl substituents. *See* MPEP §2163(II)(3). Thus, Applicants submit that the written description requirement under 35 U.S.C. §112 (1st Paragraph) is satisfied. Nevertheless, in an effort to expedite prosecution of this application, the R² definitions have been amended in accordance with the suggested amendments in the Office action, thus making this rejection moot. Specifically, in claims 1, 5, and 9, the following phrase:

"C₅-C₇ monocyclic heteroaryl ring having one to three heteroatoms selected from O, S, and N"

has been replaced with the following phrase:

“a heteroaryl selected from the group consisting of pyridinyl, pyrazinyl, pyridazinyl, pyrimidinyl, thienyl, pyrrolyl, pyrazolyl, imidazolyl, oxazolyl, and isoxazolyl”.

Claims 1, 5, and 9 also are rejected under 35 U.S.C. §112 (2nd Paragraph) because the heteroaryl definitions for R² do not recite specific heterocyclic rings. Applicants request withdrawal of this rejection. Applicants submit that their use of the term “heteroaryl” is appropriate, and that it is improper for the Patent Office to require the claims to instead recite specific heterocyclic rings. *See, e.g.*, MPEP §2173.04 (breadth of a claim is not to be equated with indefiniteness). Nevertheless, as noted above, the R² definitions in claims 1, 5, and 9 have been amended to recite specific heteroaryl rings, thus making this rejection moot.

Response to rejection of claims 2, 3, 6, and 7 for depending on rejected claims

Claims 2, 3, 6, and 7 have been rejected for depending on rejected claims. Applicants request withdrawal of this rejection. Claims 2 and 3 depend from claim 1, which Applicants submit is allowable for at least the reasons discussed above. Similarly, claims 6 and 7 depend from claim 5, which Applicants also submit is allowable for at least the reasons discussed above.

Response to rejection of claims 4 and 8 under 37 C.F.R. §1.141

Claims 4 and 8 have been rejected under 37 C.F.R. §1.141 for reciting too many compound species. The Office action suggests splitting these claims into multiple claims that are each less than one page in length. Applicants request withdrawal of this rejection. Applicants submit that the Markush groups in claims 4 and 8 are proper under the Patent Office’s guidelines. *See* MPEP §§803.02 and 2173.05(h). Applicants further submit that the burden on the Patent Office for examining the subject matter of these claims is the same regardless of whether the claims are each split into multiple claims. Thus, there is no reason for requiring these claims to each be split into multiple claims.

Nevertheless, in an effort to expedite prosecution of this application, claims 4 and 8 have been amended as suggested by the Office action, thus making this rejection moot. Specifically, the subject matter of claim 4 has been divided into four claims that are each less than a page in

length by removing the last 36 compounds from claim 4, and splitting them equally into new claims 19-21. Similarly, the subject matter of claim 8 has been divided into four claims by removing the last 36 compounds, and splitting them equally into new claims 22-24. Applicants note that these amendments do not narrow the overall scope of the claims, given that the combined scope of coverage of claims 4 and 19-21 is the same as originally-filed claim 4, and the combined scope of coverage of claims 8 and 22-24 is the same as originally-filed claim 8.

In anticipation of the subject matter of claim 12 being found to be allowable, Applicants have similarly divided the subject matter of claim 12 into four claims that are each less than one page in length by removing the last 36 compounds from claim 12, and splitting them equally into new claims 25-27. Applicants note that this amendment does not narrow the overall scope of the claims, given that the combined scope of coverage of claims 12 and 25-27 is the same as originally-filed claim 12.

Response to rejections of claim 8 under 35 U.S.C. §112 (1st, 2nd, and 4th Paragraphs)

Claim 8 has been rejected under 35 U.S.C. §112 (1st, 2nd, and 4th Paragraphs) for reciting the term “prodrug”. Applicants request withdrawal of these rejections in view of the amendments to claim 8, which delete the term “prodrug” and therefore make these rejections moot. Applicants make no representation as to the merit of any of the rejections with respect to use of "prodrug" in claim 8.

Response to rejection of claims 9-14 under 35 U.S.C. §101

Claims 9-14 have been rejected under 35 U.S.C. §101 as lacking utility. Applicants request withdrawal of this rejection. Applicants submit that claim 9, as originally filed, identifies a specific utility, *i.e.*, treating a condition mediated by the $\alpha_v\beta_3$ integrin. Nevertheless, in an effort to expedite prosecution of this application, claim 9 has been amended to characterize the treated condition as being treatable by inhibiting $\alpha_v\beta_3$ integrin. In other words, claim 9 (as amended) expressly defines the treated condition in terms of a biological activity of Applicants' compounds. This is a specific, demonstratable utility. *See* MPEP §2107.01(I) (specific utility is shown where an applicant discloses a specific biological activity and correlates that activity to a disease condition). *See also*, MPEP §2107.01(III) (acknowledging that courts have repeatedly

found that mere identification of a compound's pharmacological activity that is relevant to an asserted pharmacological use satisfies the utility requirement).

In view of the foregoing, Applicants should not be required to limit claims 9-14 to a single condition. Claims 9-14 are directed to using Applicants' compounds for a single utility (*i.e.*, inhibiting $\alpha_v\beta_3$ integrin), and should therefore be examined without restriction. Restriction of these claims to one condition, in fact, would be contrary to the Patent Office's guidelines, which require "a serious burden on the examiner" before the claims can be restricted. *See* MPEP §803. *See also*, MPEP §803.02 (requiring examination of an entire Markush group where the members of the group are sufficiently few in number or so closely related that a search and examination can be made without serious burden). Here, claims 9-14 each include all the limitations of at least one of claims 1-4. Thus, examination of the entire scope of claims 9-14 can be made without serious burden once compound claims 1-4 are found to be allowable. In fact, once claims 1-4 are found to be allowable, the entire scope of claims 9-14 must be examined pursuant to the Patent Office's Guidelines. And this examination will be mandatory even if claims 9-14 are first withdrawn pursuant to a restriction requirement:

if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which . . . include all the limitations of the allowable product claim will be rejoined.

MPEP §821.04 (emphasis added).

Response to withdrawal of claims 15-18

The Office action indicates that claims 15-18 have been withdrawn from examination. No restriction requirement, however, has been issued in this case. Thus, withdrawal of these claims from examination is improper. Moreover, claims 15-18 include all the limitations of claim 1. Applicants submit that restriction of these claims is therefore improper under MPEP §803 because examination of claims 15-18 will include little additional burden once examination of claim 1 is completed. In addition, even if these claims are withdrawn via a restriction requirement, MPEP §821.04 will require at least the method claims (*i.e.*, claims 15 and 16) to be rejoined once claim 1 is found to be allowable.

Allowable Subject Matter

Applicants acknowledge the finding of allowability as to the subject matter of claims 2-4, 6, and 7.

Information Disclosure Statement

Applicants cited three references in their December 5, 2002 Information Disclosure Statement. The Examiner initialed and signed the corresponding Form PTO-1449 on January 24, 2003. It is Applicants' understanding that the Examiner has therefore thoroughly reviewed and understood the material disclosed in each of the cited references. If this understanding is incorrect, Applicants request that the Examiner call the Undersigned.

New Correspondence Address

An associate power of attorney and a change of correspondence address have been filed for this patent application. In accordance with those documents, please send all future correspondence to the undersigned at the following address:

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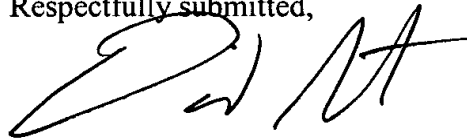
Applicants request a 2-month extension to reply to the October 6, 2003, and have enclosed a check to cover that fee. The enclosed check also includes the claim fees for the new claims (*i.e.*, claims 19-27), to the extent that the total claim number exceeds 20. Applications do not believe that they owe any additional fee in connection with this filing. If, however, Applicants do owe any fee(s), the Commissioner is hereby authorized to charge the fee(s) to Deposit Account No. **08-0750**. In addition, if there is ever any other fee deficiency or

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U.S. Appl. 09/924,732
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overpayment under 37 C.F.R. §1.16 or 1.17 in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. **08-0750**.

Applicants submit that the pending claims are in condition for allowance, and request that this application be allowed. The Examiner is requested to call the Undersigned if any issues arise that can be addressed over the phone to expedite examination of this application.

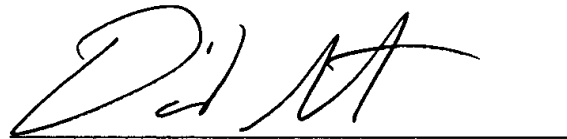
Respectfully submitted,



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CERTIFICATE OF MAILING UNDER 37 CFR § 1.8

I certify that this correspondence is being deposited with the U.S. Postal Service on **February 12, 2004** with sufficient postage as first class mail (including Express Mail per MPEP § 512), and addressed to **Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450**.



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